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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1314**

**[Docket No. DEA-347]**

**RIN 1117-AB30**

**Self-Certification and Employee Training of Mail-Order Distributors of Scheduled Listed Chemical Products**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This document finalizes the Drug Enforcement Administration's rule implementing the requirements of the Combat Methamphetamine Enhancement Act of 2010 establishing self-certification and training requirements for mail-order distributors of scheduled listed chemical products. This action finalizes without change the interim final rule with request for comment published on April 13, 2011.

**DATES:** This rule takes effect [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22512; Telephone: (202) 598-6812.

## **SUPPLEMENTARY INFORMATION:**

### **Legal Authority**

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, but they are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purposes of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States.

The CSA grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals, 21 U.S.C. 821, and the efficient execution of his statutory functions. 21 U.S.C. 871(b). The Attorney General has delegated this authority to the Administrator of the DEA, 28 CFR 0.100(b), who in turn has redelegated certain authorities to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”), 28 CFR part 0, appendix to subpart R.

By this document, the DEA finalizes the interim final rule, “Self-Certification and Employee Training of Mail-Order Distributors of Scheduled Listed Chemical Products” published on April 13, 2011, at 76 FR 20518. This rule became effective on April 13, 2011. The interim final rule solicited public comments for which the comment period

closed on June 13, 2011. No comments were received in response to the publication. No changes are being made to the rule.

## **Background**

The preamble to the interim final rule explained that section 2 of the Combat Methamphetamine Enhancement Act of 2010 (MEA) (Pub. L. No. 111-268, 124 Stat. 2847) amended 21 U.S.C. 830(e)(2) to establish new requirements for mail-order distributors to self-certify with the DEA in order to sell scheduled listed chemical products at retail. Sales “at retail” are those intended for personal use. 21 U.S.C. 802(48); 21 CFR 1300.02(b). As Congress directed in the MEA, the DEA has established through this rule criteria for certifications of mail-order distributors consistent with the criteria previously established for certifications of other regulated sellers.<sup>1</sup> The self-certification must include a statement that the mail-order distributor understands the requirements applicable under 21 CFR part 1314 and agrees to comply with those requirements. Prior to certification, mail-order distributors of scheduled listed chemical products are required to provide the DEA-developed training (available at the DEA’s Web site) to their employees.

The MEA is the most recent in a series of legislative actions aimed at preventing illicit drug manufacturers’ access to methamphetamine precursor chemicals and enhancing penalties for methamphetamine production and trafficking. Methamphetamine is a highly addictive stimulant drug in schedule II of the CSA. As recognized through the

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<sup>1</sup> The DEA initially established criteria for certifications for regulated sellers pursuant to the Combat Methamphetamine Epidemic Act of 2005 (CMEA), Pub. L. No. 109-177, 120 Stat. 256. The DEA implemented the retail sales provisions of the CMEA through Interim Final Rule, “Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products,” published Sept. 26, 2006 at 71 FR 56008; corrected at 71 FR 60609, Oct. 13, 2006.

acts of Congress, the clandestine manufacture and distribution of methamphetamine have been and continue to be serious national public health problems.<sup>2</sup>

### **Who are “Mail-Order Distributors” Subject to the Training and Self-Certification Requirements?**

The MEA refers to “mail-order distributors” but does not define the term. As stated in the interim final rule, the idea of mail-order distributor is developed in 21 CFR part 1314, which discusses regulated persons who make a sale at retail of a scheduled listed chemical product and are required under § 1310.03(c) to submit a report of the sales transaction to the Administration. 21 CFR 1314.100(a). The CSA and its implementing regulations impose recordkeeping and reporting requirements on regulated persons who engage in transactions with a nonregulated person or who engage in an export transaction involving ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and who use or attempt to use the Postal Service or any private or commercial carrier. 21 CFR 1310.03(c). Of those subject to the recordkeeping and reporting requirements, only those distributors who engage in mail-order sales at retail of scheduled listed chemical products are subject to the training and self-certification requirements. 21 CFR 1314.101 and 1314.102. A “mail-order sale,” for purposes of part 1314, is defined by DEA regulations as a retail sale of scheduled listed chemical products for personal use where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer. 21 CFR 1314.03. Mail-order sales include purchase orders submitted by phone, mail, fax, Internet, or any method other than a face-to-face

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<sup>2</sup> *E.g.*, H.R.REP. NO. 109-299, pt. 2 (2005); For a summary of effects of methamphetamine abuse and addiction see NIDA InfoFacts: Methamphetamine (available at <http://www.drugabuse.gov/publications/drugfacts/methamphetamine>).

transaction. *Id.* The terms “regulated person,” “scheduled listed chemical product,” and “at retail” are defined in 21 U.S.C. 802.

The DEA is taking this opportunity in publishing this final rule to provide in this supplementary information a clearer discussion of the development of the statutory and regulatory requirements relating to “mail-order distributors” than was included in the preamble of the interim final rule. Before 1996 persons now labeled as “mail-order distributors” were not subject to specific regulation as a distinct group. Beginning in 1996, Congress has imposed a number of requirements on these distributors, specifically, in such laws as the Comprehensive Methamphetamine Control Act of 1996 (CMCA), Pub. L. No. 104-237, 110 Stat. 3099; the Methamphetamine Anti-Proliferation Act of 2000 (MAPA), Pub. L. No. 106-310, 114 Stat. 1227; the Combat Methamphetamine Epidemic Act of 2005 (CMEA), Pub. L. No. 109-177, 120 Stat. 256; and the MEA.

The CMCA established monthly reporting requirements applicable to regulated persons who engage in transactions with nonregulated persons involving ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals) and use or attempt to use the Postal Service or any private or commercial carrier. 21 U.S.C. 830(b)(3)(B). The DEA implemented the monthly reporting requirement at 21 CFR 1310.03(c). The MAPA amended 21 U.S.C. 830(b)(3)(B) to require regulated persons also to report mail-order export transactions involving ephedrine, pseudoephedrine, and phenylpropanolamine.

The MAPA also established exemptions from the mail-order reporting requirements, including an exemption relating to non-“face-to-face” transactions. 21 U.S.C. 830(b)(3)(D)(ii). That exemption stipulates that retail distributors generally are not

required to report non-face-to-face sales of U.S. Food and Drug Administration-approved (FDA-approved) drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine to ultimate users if the seller's activities related to those products are almost exclusively confined to sales for personal use, both in terms of number and volume of sales. *Id.*; 21 U.S.C. 802(49). Subsequently, the CMEA specified, however, that this clause is not applicable to sales of scheduled listed chemical products at retail. 21 U.S.C. 830(b)(3)(D)(ii). The DEA interprets this to mean that "retail stores that deliver these products to customers by mail or delivery services will need to comply with the provisions for mail order sales reporting for these transaction[s]." 71 FR 56008, 56011, Sept. 26, 2006.

Certain additional requirements apply to mail-order distributors. For instance, under the CMEA, mail-order distributors making retail sales of scheduled listed chemical products must confirm the purchaser's identity and may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in scheduled listed chemical products per customer during a 30-day period. 21 U.S.C. 830(e)(2)(A)–(B). Most recently, the MEA added the requirement that mail-order distributors self-certify in order to sell scheduled listed chemical products at retail, and makes it unlawful for any person to negligently fail to self-certify as required under section 830. 21 U.S.C. 830(e)(2)(C) and 842(a)(10).

### **Which Locations are subject to the Self-Certification requirement?**

Section 2 of the MEA, codified at 21 U.S.C. 830(e)(2)(c), requires the Attorney General to establish by regulation "criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers"

under the CMEA. The CMEA specifies that a separate certification is required for each place of business at which scheduled listed chemical products are sold at retail. 21 U.S.C. 830(e)(1)(B)(ii)(II); 21 CFR 1314.40(c). The DEA analyzed the plain language and purpose of the statute to interpret the meaning of “each place of business” where retail sales are made.<sup>3</sup> As described in the interim final rule, DEA concludes that mail-order distributors are required to certify at: (1) every location that prepares or packages product for distribution to customers, and (2) every location where employees accept payment for such sales. This interpretation is consistent with the intent of the MEA to ensure that mail-order distributors of scheduled listed chemical products are aware of their recordkeeping, reporting, customer identification, and sales limit requirements.

### **Regulatory Analyses**

#### *Executive Order 12866 (Regulatory Planning and Review)*

This regulation has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation. It has been determined that this is not “a significant regulatory action.” As discussed above, and in the interim final rule, this action is codifying statutory provisions and involves no agency discretion as to regulatory alternatives. As analyzed in the interim final rule at 76 FR 20158, the DEA has determined that the MEA’s requirements will not impose an annual cost on the economy of \$100 million or more, the standard for an economically significant rule under Executive Order 12866. The DEA received no public comments with respect to the interim final rule.

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<sup>3</sup> The DEA notes that this statutory language is materially different than the language requiring entities that manufacture, distribute, or dispense controlled substances or list I chemicals to register at “each *principal* place of business *or professional practice*.” 21 U.S.C. 822(e). The intent and rationale for the two requirements are different, as well.

### *Paperwork Reduction Act of 1995*

To address the new mandates of the MEA, the DEA has revised its existing information collection “Self-Certification, Training and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products,” Information Collection 1117-0046. The MEA requires mail-order distributors to train any employee who will be involved in selling scheduled listed chemical products and to document the training. Mail-order distributors must also self-certify to the DEA that all affected employees have been trained and that the mail-order distributor is in compliance with all provisions of the CMEA. No comments were received by the DEA regarding the information collection.

### *Regulatory Flexibility Analysis*

The Deputy Assistant Administrator, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. As noted in the interim final rule, the RFA applies to rules that are subject to notice and comment. The DEA determined, as explained in the interim final rule, that public notice and comment were impracticable and contrary to the public interest. Consequently, the RFA does not apply.

Although the RFA does not apply to this rulemaking, the DEA has reviewed the potential impacts in the interim final rule, in which the DEA certified that the rule will not have a significant economic impact on small entities. As published in the interim final rule, based on reports filed, DEA expects that the rule will affect only 9 firms, two of which are not small based on the Small Business Administration's size standards. For



the seven small firms, the only costs are the \$21 annual fee, the time required to complete the certification (0.5 hours or about \$20 for a new self-certification application), and cost of training (0.5 hours or about \$10). The cost of compliance for these firms, which appear to have between 5 and 25 employees, not all of whom would need to be trained, is less than \$200 and in most cases, less than \$100. The smallest mail order pharmacies (those with fewer than five employees) have average annual sales of \$1 million. The cost of compliance is, therefore, less than 0.1 percent of sales and would not impose a significant economic burden on any small entity.

The DEA received no public comments with respect to the interim final rule and the DEA has not received any other information that would materially change the impact of this rule on small entities. Therefore, the DEA concludes this rulemaking will not have a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995*

This rule will not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, 109 Stat. 48). This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*EO 12988 (Civil Justice Reform)*

This regulation meets the applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

#### *Executive Order 13132 (Federalism)*

This rulemaking has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and the DEA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This rulemaking does not impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. The requirements of this rule are mandated under the MEA, and the DEA has no authority to alter them or change the preemption. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

#### *Executive Order 13175 (Tribal Consultation)*

The DEA has analyzed this action under Executive Order 13175 and this rule will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal law. Therefore, a tribal summary impact statement is not required.

#### *Congressional Review Act*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100 million or more. It will not cause a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

### **List of Subjects in 21 CFR Part 1314**

Drug traffic control, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 21 CFR part 1314 which was published at 76 FR 20518 on April 13, 2011, is adopted as a final rule without change.

Dated: January 19, 2016.

Louis J. Milione,  
*Deputy Assistant Administrator, Office of Diversion Control.*  
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